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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,706	09/08/2000	Randall B. Lauffer	MET/7 CON	3760

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FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER

HARTLEY, MICHAEL G

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,706

Applicant(s)

LAUFFER ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64,65,67 and 71-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64, 65, 67, 71-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1616

Response to Amendment

The amendment filed 5/27/2003 has been entered. Claims 66 and 68-70 have been canceled. Claims 64, 65, 67, 71-83 have been amended. New claim 84 has been added. The specification has been amended as requested.

Response to Arguments

Any previous rejection that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64, 65, 67, 71-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the office action mailed 1/21/2003.

Applicant's arguments filed 5/27/2003 have been fully considered but they are not persuasive.

Applicant asserts that there is no lack of structural relationship because specific chelating moieties, i.e., DTPA, DOTA, etc. are bound to a structure $-(L)_m$ -SDTBM.

This is not found persuasive because it is not the entire structure which omits the essential structural relationship, but the SDTBM. There is no structural relationship of elements (or chemical moieties) which make up the SDTBM. For example, the SDTBM is defined only that it comprises (which is open-ended language) various numbers (i.e., 1 to 5) chemical moieties and combinations thereof. However, it is unclear how these chemical moieties are structurally related, i.e., how they are bound to each other. It is unclear how one or more of the alkyl groups is bound of another alkyl group or a aryl group or a cycloalkyl group, etc. The SDTBM is claimed just by some pieces which are present. However, there is nothing in this definition on how the pieces may be put together to provide a structural relationship. Further complicating this definition is the use of open ended language "comprising" which implies that various other chemical moieties may be present. Therefore, it cannot be determined what chemical structures are being claimed or excluded by the definition of the SDTMB as claimed.

Art Unit: 1616

Further, the claim recites that "zero" of each group of chemical moiety may be present. Thus, the SDTBM may be nothing. It is unclear how this moiety can be defined as nothing.

The dependent claims fall therewith.

Applicant's arguments with respect to claims 64, 65, 67, 71-84 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64, 65, 67, 71-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The definition of the SDTBM that is comprises "zero to six linear or branched alkyl groups having 1 to 10 carbon atoms; zero to five cycloalkyl groups, zero to five aryl groups..." was not described in the specification. The specification fails to describe the SDTBM in this manner. The specification describes the SDTBM on page 19 as "a small molecule or a biomolecule" but fails to describe the SDTBM as now claimed. Also, the SDTBM, now may comprise "zero" of any of the recited groups. Thus, it may contain nothing. There is no description of the SDTBM as containing the number of chemical groups now claimed, let alone zero of the groups. Further, since this limitation recites "comprising" it is open-ended, therefore, the SDTBM may be any molecule which contain zero to five of the recited groups, arranged in any fashion, and therefore unlimited. There is no description in the specification of the SDTBM of being any chemical moiety, just as long as it comprises form zero to five of the chemical moieties as now recited.

The dependent claims fall therewith.

Art Unit: 1616

Conclusion

No claims are allowed at this time.

The claims are free of the art of record. While chelating agents having a structure encompassed by the instant claim language may be known, the prior art fails to teach or suggest the use of such contrast agents in methods of MRI and interventional therapy as claimed. The prior art fails to teach or suggest that such contrast agents would be specifically useful in a method of MRI and interventional therapy, as claimed because prior art fails to teach or suggest the specific imaging steps in combination with interventional therapy using contrast agents having the specific functional limitations set forth.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

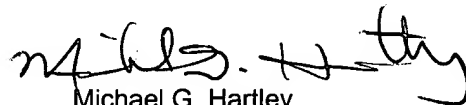
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where

Art Unit: 1616

this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "Michael G. Hartley", written in a cursive style.

Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
July 18, 2003